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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,691	06/03/2002	Stephen Gill	PA-9947	3741

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GE HEALTHCARE, INC.  
IP DEPARTMENT  
101 CARNEGIE CENTER  
PRINCETON, NJ 08540-6231

EXAMINER
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JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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12/12/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/069,691	GILL ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 September 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the amendment filed 9/28/07 wherein claim 1 was amended.

**Note:** Claims 1-14 are pending.

## **RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS**

2. The Applicant's arguments and/or amendment filed 9/28/07 to the rejection of claims 1-14 made by the Examiner under 35 USC 103 have been fully considered and deemed non-persuasive for reasons of record in the office action mailed 6/29/07 and those set forth below.

### **103 Rejections**

The rejection of claims 1-14 under 35 USC 103(a) as being unpatentable over Crane (US Patent No. 5,951,952) in view of Yamaguchi et al (JP 11-99192) in further view of Schott Glaswerke (DE 29609958) or Walther (US Patent No. 6,200,658) is MAINTAINED.

Applicant's assertions may be summarized as follows. (1) The Examiner points out the Jepson type claim, but the Examiner's characterization of the claim is incorrect. Applicant has amended the claims and asserts that the novelty of the instant invention is that the radiometal metal complex is in a silica coated container. (2) Applicant asserts that JP '192 would not lead to the subject matter of the instant invention. Specifically, amended claim 1 makes it clear that an organic ligand which forms a coordination complex with the radiometal must be present. In addition, Applicant is unsure why the Examiner has focused on an analysis of the novelty of a feature of the

present claims when the issue at stake is an obviousness issue. (3) Applicant asserts that JP '192 teaches only solving adsorption problems for ionic radiopharmaceuticals which are not metal complexes. (4) Applicant asserts that the Examiner's logic about the combining of the references is not obvious. Also, Applicant asserts that the Examiner's logic ignores the issues of the suitability of the combination and motivation to combine. In addition, Applicant asserts that while the Examiner has responded to Applicant's hindsight assertions before, the Examiner has disregarded all alternatives apart from those which lead to the instant invention.

Essentially, the same arguments presented in earlier responses are once again presented. As previously stated, Applicant's attention is directed to the Examiners' responses of each of the previous office actions. While Applicant asserts that the Examiner should point to specific arguments, it should be noted that the same arguments are being presented and the Examiners' responses are being maintained. Furthermore, since each office action is a part of the official record, it is not necessary for the Examiner to write or restate each response each time word for word when the responses are already of record.

The Examiner discussed in detail Jepson type claims to illustrate that not all portions of the claim are considered novel. The portion of the claim that is 'novel' that which follows the phrase 'the improvement comprising' found between the preamble and the body of the claim. The Examiner then went on to discuss the prior art and how it relates to the instant invention.

First, it is noted that the claims have been amended to specifically state that the radiopharmaceutical comprises a coordination complex of a metal with an organic ligand whereas previously the claim read 'the radiopharmaceutical includes a metal complex. Thus, the claims did not exclude radioactive thallium chloride, etc. complexes, neither did independent claim 1 require the presence of an organic ligand. However, even though the claims have been amended, the teachings of JP '192 still are applicable. For example, as previously stated, JP '192 establishes that Containers for pharmaceuticals which can prevent highly adsorbable radiopharmaceuticals from being adsorbed thereon and provide a clear description of their contents and the amounts thereof wherein the container for radiopharmaceuticals is characterized in that the interior surface of a glass container is coated with silica is well known in the art. In addition, JP '192 establishes that in the prior art radioactive materials are used as tracers for diagnostic imaging and in some cases a single element is used as the radioactive material and in other cases they are used by labeling compounds which show specific behavior in vivo (see page 4, paragraph [0002]). Thus, the teaching of using a metal complex in combination with a silica coated container is established. Furthermore, as set forth in the office action mailed 11/29/05, the Examiner stated that it Crane et al sets forth that metal complexes as radiopharmaceuticals are well known in the art and since both JP '192 and Crane et al disclose metal complexes, even though they are not identical complexes, it is not clear why the advantage disclosed by JP '192 would not hold true for metal complexes of Crane et al as well. Specifically, JP '192 discloses the advantage of preventing adsorption of the container surface with that of

the radiopharmaceutical. The Examiner further stated that one skilled in the art would expect similar advantages from various radiopharmaceuticals, as JP '192 does not limit its teaching one specific radiopharmaceutical, but teaches that coating the inner surface of the vial with silica provides the advantage of accurate measuring of the radiopharmaceutical. This advantage would be expected with any radiopharmaceutical and the relevance of whether or not radiopharmaceutical is a metal complex such as that of Crane et al or that of JP '192 is not seen since this would not appear to change the measurement advantage. The Examiner went on to state that the cited prior art as a whole as shown by the secondary references discloses that silica coated vials provide various advantages for various pharmaceutical agents. For example, Schott establishes that it is known in the art to coat a glass container with silica to avoid leaching of substances from the glass (page 1, first complete paragraph; pages 1-2, bridging paragraph; page 2, third and fourth paragraphs). Thus, while the diagnostic agent of Schott is not necessarily the same as Applicant, the reference like JP '192, teaches a silica coated container in combination with a diagnostic agent. Therefore, the teachings necessary for the instant invention are known in the art and the interchanging of diagnostic agents in a silica coated container is within the skill of a practitioner in the art.

Without repeating word for word the Examiner's arguments for Applicant's hindsight assertion, the Examiner once again asserts that the prior art disclose a diagnostic agent like the one being claimed by Applicant in a coated container. Thus, in those documents, for example, one would be motivated to place a known diagnostic

agent in an 'improved' container with a silica coating known to have various advantages.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



D. L. Jones  
Primary Examiner  
Art Unit 1618

December 9, 2007